UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,881	01/03/2007	Laurence Feruccio	REG-06-1474	1577
	7590 01/14/200 DLA PIPER US LLP	EXAMINER		
ONE LIBERTY	<del>-</del> -	ELHILO, EISA B		
PHILADELPH	ST, SUITE 4900 IA, PA 19103		ART UNIT	PAPER NUMBER
			1796	
			MAIL DATE	DELIVERY MODE
			01/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary		Applica	tion No.	Applicant(s)	Applicant(s)			
		10/586,	881	FERUCCIO ET AL				
		Examin	er	Art Unit				
		Eisa B.	Elhilo	1796				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
	Responsive to communication(s) file	nd on 03 January 20	207					
2a)□	Responsive to communication(s) filed on <u>03 January 2007</u> .  This action is <b>FINAL</b> . 2b) This action is non-final.							
3)□		<i>'</i> —		ters prosecution as to the	marite is			
3)[	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	·	oo anaor Ex pareo c	kuuyio, 1000 O.L	5. 11, 100 0.0. 210.				
	on of Claims							
·—	Claim(s) <u>20-40</u> is/are pending in the							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
'=	5) Claim(s) is/are allowed.							
· · —	6) Claim(s) <u>20,21,25-30 and 35-40</u> is/are rejected.							
	Claim(s) <u>22-24 and 31-34</u> is/are objective.							
8)[_]	Claim(s) are subject to restrict	ction and/or election	requirement.					
Applicati	on Papers							
9)	The specification is objected to by the	e Examiner.						
10)	The drawing(s) filed on is/are:	a) <u></u> accepted or l	b)∏ objected to	by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority ι	ınder 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
2)  Notic 3) Inform	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (F nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>1/3/2007</u> .	PTO-948)	Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application 				

Application/Control Number: 10/586,881 Page 2

Art Unit: 1796

Claims 20-40 are pending in this application.

### **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 35-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the limitation "in which Z, Y and n". There is insufficient antecedent basis for this limitation in the claim because the claimed formula (I) does not comprise the limitation "n". Correction and/or clarification are requested.

Claims 35, 37, 38 and 39 are indefinite because the claims recite the limitations "compound of formula (I)". It is unclear if these claims are dependent on claim 20 or not? If these claims are independent claims then each claim should recite a separate formula. Correction or clarification is requested.

Claims 36 and 40 are dependent claims. Therefore, these claims are rejected as well.

# Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Page 3

Art Unit: 1796

Claims 20-21, 25-27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated Leydet et al. Journal of Medicinal Chemistry, 1995).

Leydet et al. (J. Med. Chem.) teaches a compound having a formula identical to the claimed formula (I) as claimed in claims 20, 21, 25 and 26 (see STIC Search Report at page 27, the upper two formulae). Leydet et al. also teaches a process for synthesizing the compound as claimed in claims 27 and 30 (see page 2434, Scheme 2 in the J.Med.Chem.). Leydet et al. teaches all the limitations of the instant claims. Hence, Leydet et al. anticipates the claims.

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leydet et al. (Journal of Medicinal Chemistry, 1995).

The disclosure of Leydet et al. (J. Med. Chem.) as described above, teaches the process for synthesizing the compounds of the claimed formula (1) (see page 2434, Scheme 2 in the J.Med.Chem.).

The instant claims differ from the reference by reciting the temperatures of the reaction.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply such a process with the claimed temperatures to arrive at the claimed invention because the reference clearly teaches similar process that involves similar

Art Unit: 1796

reactant compounds of alcohol and acid anhydride, and, thus a person of the ordinary skill would expect such a process to have similar properties to those claimed, absent unexpected results.

## Allowable Subject Matter

Claims 22-24 and 31-34 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record do not teach or disclose the limitations of these claims.

#### Conclusion

The remaining references listed on from PTO-1449 have been reviewed by the examiner and are considered to be cumulative to or less material than the prior art references relied upon in the rejection above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eisa B. Elhilo whose telephone number is (571) 272-1315. The examiner can normally be reached on M - F (8:00 -4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Pyon Harold can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

Application/Control Number: 10/586,881 Page 5

Art Unit: 1796

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eisa B Elhilo/ Primary Examiner, Art Unit 1796 January 8, 2009

•